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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,237	07/17/2003	Peter Robert Baum	2873-USA	4633

22932 7590 07/15/2005

IMMUNEX CORPORATION  
LAW DEPARTMENT  
1201 AMGEN COURT WEST  
SEATTLE, WA 98119

EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/622,237

Applicant(s)

BAUM ET AL.

Examiner

Maher M. Haddad

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18 and 20-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 18 and 20-23 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/20/05.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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## RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 4/20/05, is acknowledged.
2. Claims 18 and 20-23 are pending and under examination in the instant application.
3. In view of the amendment filed on 4/20/05, only the following rejections are remained.
4. The IDS filed, 4/20/05 is acknowledged, however, references A2, A3 and C2 are duplicates of the references cited by the Examiner on the Form 892 mailed 7/28/04.
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.*

*The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).*

*(e1) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

*35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).*

6. Claims 18 and 20-23 are rejected under 35 U.S.C. 102(e2) as being anticipated by U.S. Patent No. 6,642,360, as is evidenced by Bost et al for the same reasons set forth in the previous Office Action mailed 7/28/04.

Further, the '360 patent teaches a composition of matter comprising an anti-PRO355 antibody (see col. 19 lines 24-30 in particular).

7. Claims 18 and 20-23 are rejected under 35 U.S.C. 102(e1) as being anticipated by Pub. No. U.S. 2002/0198147 A1, as is evidenced by Bost et al for the same reasons set forth in the previous Office Action mailed 7/28/04.

Further, the '360 patent teaches a composition of matter comprising an anti-PRO355 antibody (see paragraph 140 in particular).

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Applicant's arguments, filed 4/20/05, have been fully considered, but have not been found convincing.

Applicant submits that the '360 patent and the '147 publication are not prior art because applicants' date of invention antedates the earliest effective filing date of the references. Applicant provides a declaration under 37 CFR 1.131 which show that Applicants were in possession of SEQ ID NO: 2 and 4 prior to December 3, 1997, which is prior to the earliest effective filing date for either of the cited references. Applicant concludes that the '360 patent and the '147 publication are not prior art.

However, the declaration filed under 37 CFR 1.131 by Drs. Peter Robert Baum and William Christian Fanslow III on 4/20/05 is insufficient to antedate both the '360 patent and the '147 publication because the declaration is directed to the amino acid sequence of SEQ ID NO:2, however, the claims are directed to antibodies to SEQ ID NO:2. It is unclear from the declaration when the claimed antibodies are made. The Declaration only provides for the antigen. Therefore, both the '360 patent and the '147 publication are prior art.

8. The following new ground of rejections are necessitated by the amendment submitted 4/20/05.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

10. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The "antibody of claim" recited in claims 21-23 has no antecedent basis in base claim 18 and 22. Base claim 18 only recites a composition.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

12. Claims 18, 20-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

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The word "composition" claimed in claims 18 and 20 and the phrase "the antibody specifically binds to extracellular domain of SEQ ID NO: 2" claimed in claim 22 represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed 4/20/05 points to the specification at page 3, lines 28-37 for support for the newly added limitations "composition" as claimed in claim 18 and 20 and "the antibody specifically binds to extracellular domain of SEQ ID NO: 2" as claimed in claim 22. However, the specification does not provide a clear support for such limitations. The Examiner noted that the specification provides a composition for the polypeptide but not for the antibodies. Further, the specification discloses antibodies to SEQ ID NO: 2 but not to the extracellular domain of SEQ ID NO: 2. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.  
Patent Examiner  
June 28, 2005

  
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